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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/594,923 | 05/02/2007 | Naohisa Tachiya | Q97359 | 5287 |

23373 7590 04/15/2011

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| EXAMINER | |
|---|---|
| O SULLIVAN, PETER G | |
| ART UNIT | PAPER NUMBER |
| 1621 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 04/15/2011 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/594,923 | TACHIYA ET AL. | |
| | Examiner | Art Unit | |
| | PETER O'SULLIVAN | 1621 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *23 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *2-5,12,13 and 18-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-5,12,13,18,19 and 21* is/are rejected.

7)☒ Claim(s) *20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 2-5, 12, 13 and 18-21 are pending in this application which should be reviewed for errors. The examiner has not received the documents referred to as attached in the applicants' response.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-5, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Takayanagi, US 5945,564. Applicants' response has been given due consideration, but is considered non-persuasive. Takanagi et al. in lines 28 and 29 of column 4, disclose the use of pharmaceutically acceptable acids. One of ordinary skill in the art would also know how to prepare the free base of a compound and add various acids to produce the various salts as shown, for example, in the 103 rejection.

Claims 2-5, 19 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoshida et al, US 5,489,572. Applicants' arguments have been given due consideration, but are found non-persuasive. The comments given above are applicable here as well.

Claims 2-5, 19 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuramochi et al, US 5,661,111. Applicants' arguments have been given due consideration, but are found non-persuasive. The comments given above are applicable here as well.

Claims 2-5, 1- and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Tanaka et al., US 5,298,482. Applicants' arguments have been given due consideration, but are found non-persuasive. The comments given above are applicable here as well.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Disuke et al., JP 5310657, taken with Takayanagi, US 5945,564, Kuramochi et al, US 5,661,111, and Tanaka et al., US 5,298,482. Applicants' arguments have been given due consideration, but are found non-persuasive. The comments given above are applicable here as well. Additionally it would have been obvious to to use the process of Disuke et al. to refine 5-levulilnic acid, to mix with appropriate acids and to expect to

produce applicants' salts in view of the teaching of the secondary references those salts are useful.

Claim 20 is allowable, but objected to as dependent on a rejected claim.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Peter G. O'Sullivan at telephone number (571)272-0642.

/Peter G O'Sullivan/

Primary Examiner, Art Unit 1621